

AMENDMENTS TO THE CLAIMS:

The following Listing of Claims replaces all prior versions, and listings, of claims.

LISTING OF CLAIMS

1. (Previously Amended) A liquid, aqueous composition comprising:

- (i) a factor VII polypeptide;
- (ii) an agent suitable for keeping pH in the range of from about 5.5 to about 7.0;
- (iii) a calcium salt in a concentration of at least 200 mM, such that the composition is hypertonic;

wherein said composition has decreased formation of heavy chain fragments upon storage of said aqueous composition for 6 months at 2-8°C as compared with non-hypertonic compositions and wherein said factor VII polypeptide retains at least 50% of its initial biological activity.

2. (Previously Amended) A composition according to claim 1, further comprising (iv) an ionic strength modifying agent.

3. (Original) A composition according to claim 2, wherein the ionic strength modifying agent (iv) is selected from the list of: a neutral salt, e.g., sodium chloride; an amino acid; or a small peptide, or a mixture of at least two of said modifying agents.

4. (Original) A composition according to claim 3, wherein the ionic strength modifying agent (iv) is sodium chloride.

5. (Cancelled).

6. (Original) A composition according to claim 2, wherein the agent (iv) is present in a concentration of at least about 5 mM.

7. (Original) A composition according to claim 1, wherein the calcium salt is selected from the group consisting of: calcium chloride, calcium acetate, calcium gluconate, and calcium laevulate.

8. (Cancelled).

9. (Cancelled).

10. (Cancelled).

11. (Previously Amended) A composition according to claim 1, wherein the tonicity modifying agent (v) is selected from the group consisting of: a neutral salt; a monosaccharide; a disaccharide; polysaccharide; a sugar alcohol; an amino acid; a peptide, and a mixture of at least two of said modifying agents.

12. (Cancelled).

13. (Cancelled).

14. (Original) A composition according to claim 1, further comprising (vi) a non-ionic surfactant.

15. (Original) A composition according to claim 14, wherein the non-ionic surfactant is a polysorbate or a poloxamer or a polyoxyethylene alkyl ether.

16. (Original) A composition according to claim 1, further comprising (vii) an antioxidant

17. (Previously Amended) A composition according to claim 16, wherein the antioxidant (vii) is selected from the group consisting of: L- or D-methionine, ascorbic acid, cysteine, homocysteine, glutathione, cystine, and cysstathionine.

18. (Original) A composition according to claim 17, wherein the antioxidant is L-methionine.

19. (Original) A composition according to claim 16, wherein the antioxidant is present in a concentration of from about 0.1 to about 5.0 mg/ml.

20. (Cancelled).

21. (Previously Amended) A composition according to claim 1, wherein the agent suitable for keeping pH in the range of from about 5.5 to about 7.0 is selected from the group consisting of acids and salts of: citrate, acetate, histidine, malate, phosphate, tartaric acid, succinic acid, MES, HEPES, Imidazol, TRIS, lactate, glycylglycin, PIPES, glycin, and a mixture of at least two of said agents.

22. (Original) A composition according to claim 21, wherein the concentration of the agent is from about 1 mM to about 50 mM.

23. (Previously Amended) A composition according to claim 22, wherein the concentration of the agent is about 10 mM.

24. (Original) A composition according to claim 1, further comprising (viii) a preservative selected from the group consisting of phenol, benzyl alcohol, orto-cresol, meta-cresol, para-cresol, methyl paraben, propyl paraben, benzalconium chloride, and benzaethonium chloride.

25. (Original) A composition according to claim 1, wherein said factor VII polypeptide is stable for at least 6 months at 2-8°C.

26. (Original) A composition according to claim 1, wherein the factor VII polypeptide is recombinantly made human factor VIIa.

27. (Cancelled).

28. (Cancelled).

29. (Original) A composition according to claim 1, wherein the factor VII polypeptide is present in a concentration of from about 0.1 mg/ml to about 10 mg/ml.

30. (Previously Amended) A method for preparing a liquid, aqueous composition of a factor VII polypeptide, comprising the step of providing the factor VII polypeptide in a solution comprising (ii) an agent suitable for keeping pH in the range of from about 5.5 to about 7.0; (iii) a calcium salt in a concentration of at least 200 mM, such that the composition is hypertonic; wherein composition retains at least 50% of its initial biological activity upon storage of said aqueous composition for 6 months at 2-8°C.

31. (Currently Amended) A method for treating a factor VII-responsive syndrome, the method comprising administering to a subject in need thereof an effective amount of an aqueous liquid composition comprising (i) a factor VII polypeptide, (ii) an agent suitable for keeping pH in the range of from about 5.5 to about 7.0; (iii) a calcium salt in a concentration of at least 200 mM, such that the composition is hypertonic; wherein said composition retains at least 50% of its initial biological activity upon storage of said aqueous composition for 6 months at 2-8°C, and wherein said factor VII-responsive syndrome is selected from the group consisting of: haemophilia A, haemophilia B, Factor Xi deficiency, Factor VII deficiency, thrombocytopenia, von Willebrand's disease, presence of a clotting factor inhibitor, surgery, intra cerebral haemorrhage, trauma, and anticoagulant therapy.

32. – 37. (Cancelled).